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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,230	03/31/2004	Joel M. Blatt	BAYER 3.0-002 CONT	9148
74144	7590	01/03/2008		
BAYER LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK, LLP 600 South Avenue West Westfield, NJ 07090			EXAMINER CHIN, CHRISTOPHER L	
			ART UNIT	PAPER NUMBER
			1641	
			MAIL DATE	DELIVERY MODE
			01/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/816,230

Applicant(s)

BLATT ET AL.

Examiner

Christopher L. Chin

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-38 is/are pending in the application.
- 4a) Of the above claim(s) 26-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-14 and 16-25 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☒ Claim(s) 2-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I – claims 2-25 in the reply filed on 10/9/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 26-38 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

2. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is vague because the recitation of "the general chemistry reagent zone" lacks antecedent support.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 2, 5, 6-13, 16, 17, 19, 22, 20, 23, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kang et al.

Kang et al (US Patent 5,559,041) discloses a chromatographic device for performing immunoassays. The embodiment shown in Figure 5 comprises a common sample application zone (310) and 6 separate test zones (311A-311F). Each test zone comprises a first filter element (312), a second filter element (314), and wicking membrane (316). The same or different reagent can be deposited in each first filter element (312), permitting either parallel tests for the same analyte or a plurality of different assays on the same sample. Each wicking membrane (316) contains an immobilized substance, as appropriate for the reagent in the first filter element associated with its corresponding wicking membrane, deposited in defined assay indicia zone (318) (col. 5, lines 1-13). The reagents in the first filter element include labeled antibodies specific for the analyte(s), buffers, detergents, and anticoagulants. The device can be used for the detection of antigens, antibodies, or haptens. The immobilized substance in wicking membrane (316) can an antibody. Analytes that can be detected with the device in hormones, such as human chorionic gonadotropin (cols. 6-7).

5. Claims 2-13, 19, and 21-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Chudzik et al.

Chudzik et al (US Patent 5,707,818) discloses a chromatographic device for performing 4 simultaneous competitive immunoassays. The device comprises a

common sample application site that links 4 unitary bibulous test strips (see Figure 1). Each test strip contains a zone with labeled analyte conjugate and immobilized antibodies specific for the labeled analyte conjugate or analyte in a sample (col. 6). The label on the analyte conjugate can be an enzyme or particle reagent (col. 5, lines 35-49). The device can be used for the detection of steroids or haptens, such as drug analytes (col. 4, lines 6-14, and col. 7, lines 15-19).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al or Chudzik et al in view of Yang et al.

See above for the teachings of Kang et al and Chudzik et al.

Kang et al and Chudzik et al differ from the instant invention in failing to teach a sample treatment pad that adjusts pH and ionic composition of a sample.

Yang et al (US Patent 5,354,692) teach a chromatographic test strip for performing immunoassays. The device includes a first permeable material (32) and a second permeable material (34) that forms part of a sample treatment pad (56). The first permeable material (32) can contain reagents to pretreat a sample including buffers that

can alter the pH of the sample (col. 10, lines 29-31). The second permeable material (34) can contain detergents which can alter the ionic composition of the sample (col. 10, lines 39-42).

It would have been obvious to one of ordinary skill in the art to incorporate the sample treatment pad of Yang et al into the device of Kang et al or Chudzik et al because the sample treatment pad provides the advantage of a more sensitive immunoassay by treating the sample to remove interfering materials and optimize sample conditions.

Allowable Subject Matter

8. Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Christopher L. Chin
Primary Examiner
Art Unit 1641

12/26/07